

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Case No. 09-590V

November 24, 2014

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NICHOLE FANKHAUSER,	*
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Petitioner,	*
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v.	*
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SECRETARY OF HEALTH	*
AND HUMAN SERVICES,	*
	*
Respondent.	*
	*
* * * * *	

Mark Theodore Sadaka, Mark T. Sadaka, LLC, Englewood, NJ, for petitioner;
Debra A. Filteau Begley, U.S. Department of Justice, Washington, DC, for respondent.

DECISION ON ENTITLEMENT¹

I. Introduction

On September 8, 2009, Nichole Fankhauser (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program (the “Program” or “Vaccine Act”)² alleging that she developed severe cramping, chest pain, back pain, vomiting, and abdominal pain as a result of receiving the human papillomavirus vaccination (“HPV” or “Gardasil”) on May 24, 2007, June 24, 2008, and September 30, 2008. See Petition at 1.

¹ Because this published decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002 § 205, 44 U.S.C. § 3501 (2006). In accordance with the Vaccine Rules, each party has 14 days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be deleted from public access.

² The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

Petitioner filed a motion for ruling on the record alleging that the Gardasil vaccines she received also caused her to develop autonomic neuropathy and fibromyalgia. See Petitioner's Motion for Decision on the Record, April 7, 2014, at 15. The medical records and other information in the record, however, do not support a finding that petitioner is entitled to compensation under the Program.

Under the Vaccine Act, petitioners may not receive compensation based solely upon their claims. In order to receive compensation, the petition must be supported by either medical records or by the opinion of a qualified physician proving a causal relationship. See § 300aa-13(a)(1). Petitioner has offered the opinion of Dr. Elizabeth Vaughan. See Petitioner's Exhibit (Pet. Ex.) 23 at 29. As described in detail below, Dr. Vaughan's opinion fails to provide preponderant evidence for the elements necessary to prove causation. For this reason, and the reasons discussed below, petitioner has failed to demonstrate that she is entitled to compensation.

II. Procedural History

The petition was filed in this case on September 8, 2009, and was initially assigned to Special Master Gary Golkiewicz. See Petition at 1. Numerous medical records were filed with the petition. Respondent filed her report pursuant to Vaccine Rule 4(c), stating that petitioner had not produced sufficient evidence or a medical opinion to establish causation. Respondent's Report (Resp. Rep't), December, 7, 2009, at 16-17. Respondent concluded that petitioner had not proven that her injuries were caused by the vaccines, and that the case was therefore not appropriate for compensation under the Vaccine Act. Id. at 2.

On August 5, 2010, petitioner filed an expert report from her treating physician, Dr. Elizabeth Vaughan, who opined that it was more than likely that the Gardasil vaccine caused petitioner to suffer a toxic reaction resulting in incapacitating pain, nausea, vomiting, fainting, muscle weakness and possible seizures. Pet. Ex. 23 at 29-30. At a status conference held on October 4, 2010, respondent stated that petitioner's expert report lacked a medical theory and that a response was not feasible at that time. See Minute Entry, October 4, 2010.

Petitioner's counsel withdrew on November 23, 2010. See Order, November 24, 2010, at 1. Petitioner's mother then represented Ms. Fankhauser pro se until February 3, 2012, when Mr. Mark Sadaka entered an appearance as counsel for petitioner. See Pet. Motion for Substitution of Attorney and ECF Designation, January 24, 2012, at 1. On July 25, 2012, petitioner reached the age of eighteen and filed a motion to amend the caption of the case, substituting herself as petitioner in place of her mother. Order, July 25, 2012, at 1.

The case was reassigned to the undersigned on January 14, 2013. At a status conference held on February 14, 2013, petitioner stated that she wished to file an amended petition alleging that she suffered an autonomic neuropathy as a result of not only receiving the Gardasil vaccine, but also the Varivax and hepatitis A vaccines. See Order, February 14, 2013, at 1. Over the next 14 months, petitioner filed six motions for extensions of time to file outstanding medical records and an expert report.

On April 7, 2014, after petitioner was unable to obtain an additional expert report, she filed a motion for a decision on the record. Respondent submitted her response to petitioner's motion for a decision on the record on May 28, 2014, stating that petitioner had not established causation and requesting that the petition be dismissed. Petitioner filed a reply to respondent's response on June 9, 2014, restating her theory on causation and requested for a motion on the record.

On August 5, 2014, the undersigned held a status conference in this case to discuss petitioner's motion for ruling on the record. The undersigned noted that petitioner had filed an expert report and motion for ruling on the record, but that respondent had not filed any responsive expert report. The undersigned ordered respondent to file an expert report in 60 days in order for there to be a complete record to rule on petitioner's motion for a decision on the record.

On November 6, 2014, respondent filed a responsive expert report from Dr. Edward Cetaruk. The case is now ripe for a ruling on petitioner's motion for judgment on the record.

III. Summary of Relevant Medical Records

Prior to receiving the vaccinations at issue in this case, Ms. Fankhauser had relatively few health issues. Pet. Ex. 18 at 8. As an infant, the documents note that she experienced abdominal pain attributed to colic, as well as outbreaks of rashes at ages nine and twelve. Pet. Ex. 5 at 18; Pet. Ex. 25 at 127-28. Petitioner's past medical history is also significant for hyperactivity/attention deficit disorder (ADHD), confusion, memory problems, and poor concentration. Pet. Ex. 25 at 8-11. Petitioner's family medical history is significant for irritable bowel syndrome (IBS) and gastrointestinal disease. Pet. Ex. 3 at 2; Pet. Ex. 24 at 9 at 155.

Petitioner received the hepatitis A, Varivax, and her first Gardasil vaccine on May 24, 2007. Pet. Ex. 25 at 1. Approximately five months later, on October 1, 2007, petitioner experienced sharp abdominal pain while playing basketball. Id. at 11. Though petitioner's abdominal pain resolved after being seen at the local emergency room (ER), her pain reoccurred two days later when she was hit and tripped at a basketball game. Id. Petitioner was diagnosed with Mittelschmerz³ pain associated with ovulation. Id.

Petitioner sought medical care four times before her second Gardasil vaccination for similar complaints of abdominal pain, but the abdominal and pelvic ultrasounds were normal with the exception of a small right ovarian cyst. Pet. Ex. 25 at 22. At a well-child visit on June 24, 2008, petitioner received her second Gardasil and hepatitis A vaccinations. Id. at 2. Her pediatrician noted that petitioner's pain "seem[ed] to always be connected to [her] cycle." Id. at 28.

Petitioner was examined by gastroenterologist, Dr. Richard Caicedo, on July 15, 2008. Pet. Ex 24 at 8-10. Her physical exam was normal. Id. His impression was possible lactose

³ "Mittelschmerz" is pain associated with ovulation, usually occurring in the middle of the menstrual cycle. Dorland's Illustrated Medical Dictionary (32nd ed. 2012).

intolerance, food protein allergy, IBS, or generalized Mittelschmerz. Id. Petitioner returned to Dr. Caicedo on August 14, 2008, complaining of food sensitivities and menstrual pain, but her lactose breath test, skin testing for food allergies, and esophagogastroduodenoscopy (EGD) returned essentially normal results. Id. at 15-17. Petitioner returned to Dr. Caicedo for further treatment after a pelvic exam revealed a retroverted/flexed uterus. Pet. Ex. 19 at 112. Petitioner underwent a gastric emptying scan which was normal. Pet. Ex. 24 at 165. On September 30, 2008, petitioner returned to her PCP, Dr. Tammie Vannoy, complaining of continued abdominal pain. Pet. Ex. 25 at 35. During this visit, petitioner received her third Gardasil vaccine. Pet. Ex. 25 at 2.

After presenting to the ER on October 4, 2008, for abdominal pain, petitioner underwent a hepatobiliary iminodiacetic acid (HIDA) scan, which showed a decreased gallbladder ejection fraction of twenty percent. Pet. Ex. 24 at 32, 156. While Dr. Caicedo explained that the HIDA scan had diagnostic limitations and that the removal of petitioner's gall bladder may not be necessary, petitioner's parents elected to have her gallbladder removed on November 5, 2008. Pet. Ex. 24 at 153. During her hospitalization, petitioner was evaluated by Dr. Jane Williams, a psychologist. Pet. Ex. 24 at 132. Petitioner's family reported that petitioner had a history of panic attacks and depression. Dr. Williams's impression was "psychological factors impacting physical condition." Id. Following petitioner's surgery, Dr. John Petty recommended that petitioner follow up with gastroenterology and psychology after her symptoms did not substantially improve following her gallbladder removal. Pet. Ex. 24 at 48. He noted that petitioner's gallbladder was "clearly not the only factor" explaining her symptoms. Id. at 49.

Petitioner continued to experience abdominal pain and vomiting for the remainder of the year. After multiple visits to Dr. Vannoy, the ER, and pediatric gastroenterologist, Dr. Joseph Clark, petitioner still had normal test results following X-rays, blood work, an MRI, and physical examinations. Pet. Ex. 24 at 50, 57; Pet. Ex. 25 at 40. An upper gastrointestinal (GI) endoscopy and colonoscopy showed slight chronic gastritis, but no colon inflammation. Pet. Ex. 6 at 14. Dr. Vannoy referred petitioner to counseling. Pet. Ex. 25 at 45.

In 2009, petitioner sought treatment from multiple care providers. She presented to Yale University Medical Center for pancreatic testing. Pet. Ex. 18 at 8. While an endoscopic retrograde cholangiopancreatography (ERCP) showed increased biliary duct pressure, pancreatic function tests performed the next day were normal and showed no evidence of pancreatitis. Id. at 58, 74. Petitioner presented to the Duke University Hospital ER five days later for acute worsening of her abdominal pain where she was hospitalized from January 19, 2009, until February 5, 2009. Pet. Ex. 22 at 44. Though an upper GI endoscopy was interpreted to be consistent with pancreatitis, her treating doctors noted that petitioner's pain was noticeably improved when she was distracted by friends or family. Id. at 45. They opined that there was a "considerable stress and anxiety component" to petitioner's pain. Id. Petitioner was hospitalized again on March 13, 2009, and evaluated by Dr. Riaz Chowdhury and Dr. Brian Smith, who both opined that pancreatitis was unlikely. Pet. Ex. 19 at 38-39. Dr. Smith advised petitioner to follow up with a psychiatrist. Id. at 39.

On March 20, 2009, petitioner's mother called petitioner's PCP to request the lot numbers of petitioner's Gardasil vaccines, stating that she believed the vaccines were the cause

of petitioner's health problems. Pet. Ex. 25 at 110. On March 31, 2009, Dr. Laurence Webster stated that he believed petitioner's symptoms were related to her Gardasil vaccination. Pet. Ex. 20 at 41. However, Dr. Webster surrendered his medical license in response to an investigation by the North Carolina state medical board, and Dr. Elizabeth Vaughan took over petitioner's treatment. See Resp't's Exhibit A at 4-6. Dr. Vaughan listed "toxic effects of vaccine-Gardasil" as one of petitioner's medical issues. Pet. Ex. 23 at 3. On April 14, 2009, after several weeks of psychological counseling, petitioner reported to her counselor that "staying busy and keeping the thoughts of pain out of her head" eased her pain. Pet. Ex. 5 at 15.

Petitioner continued to seek treatment for intermittent abdominal pain as well as for new symptoms throughout 2009 and 2010. In April 2010, Dr. Anthony L. Masciello admitted petitioner to Forsyth Medical Center for severe abdominal pain after noting that she was "completely inconsolable," and recommended petitioner's family consider a psychiatric evaluation. Pet. Ex. 19 at 228. In July 2010, petitioner began reporting syncope events that usually occurred when she was exercising or overheated. Pet. Ex. 25 at 172; Pet. Ex. 20 at 2. Beginning in November 2010, petitioner was treated for lower back pain and muscle spasms for three months. Pet. Ex. 19 at 229. Dr. William Bryan Jennings, one of petitioner's treating physicians at this time, opined that the Gardasil vaccination was not related to her symptoms. Pet. Ex. 2 at 1.

Throughout 2011, petitioner reported continuous abdominal pain and vomiting, as well as rashes and muscle spasms. Pet. Ex. 15 at 25; Pet. Ex. 3 at 2; Pet. Ex. 15 at 5. A gastroenterologist reviewed petitioner's medical records and opined that her abdominal pain was likely caused by irritable bowel syndrome (IBS). Pet. Ex. 28 at 1, 2, 11. Dr. Sanjay Kumar Jain, one of petitioner's treating physicians at Johns Hopkins, opined that her symptoms were not consistent with an adverse reaction to a vaccine. Pet. Ex. 30 at 3. Petitioner's cardiologists, Dr. Chad B. Stewart and Dr. Ronald J. Kanter, opined that petitioner might have an autonomic disorder that is "markedly exacerbated by emotional and psychiatric disorders." Pet. Ex. 22 at 406.

In 2012, petitioner presented to an immunologist who conducted a comprehensive immunological workup returning normal results. Pet. Ex. 22 at 393-402, 442. Autonomic dysfunction testing was also normal. Pet. Ex. 33 at 6, 15, 83-84, 92, 129, 182.

In November 2013, physicians at Johns Hopkins stated that petitioner's symptoms were most consistent with fibromyalgia. Pet. Ex. 36 at 1. Petitioner was also told that her chest pain, dizziness, and occasional syncope were likely related to anxiety and panic attacks, while her abdominal pain was likely related to IBS. Id. at 5. Her physicians noted that she might have postural orthostatic tachycardia syndrome (POTS), but no evidence suggested this condition was organic in nature. Id. at 13.

IV. Standards for Adjudication – Causation

Special masters may determine whether a petitioner is entitled to compensation based upon the record. A hearing is not required. 42 U.S.C. § 399aa-13; Vaccine Rule 8(d). To be

awarded compensation under the Vaccine Act, a petitioner must prove either: 1) that she suffered a “table injury” – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question, which creates a presumption that the injury was caused by the vaccination, or 2) that her medical problems were caused by the vaccine(s) at issue. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). A petitioner may not be awarded compensation based on the petitioner's claims alone. 42 U.S.C. § 300aa-13(a)(1). Rather, the petition must be supported by either medical records or by the opinion of a competent physician. Id.

Because a petitioner cannot prevail based on a showing that she has suffered a “table injury,” the petitioner bears the burden of proving that the vaccination caused the injury for which she seeks compensation. Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required; a preponderance of the evidence suffices. Bunting v. Sec’y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner must demonstrate that the vaccination was a substantial factor in causing her injuries. Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1321-22 (Fed. Cir. 2010). To do this, petitioner “must show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Moberly, 592 F.3d at 1322 (quoting Althen, 418 F.3d at 1278).

A. Althen Prong One

Althen Prong One requires that petitioner set forth a medical theory causally connecting the vaccination and the injury. Althen, 418 F.3d at 1278. While petitioner asserts that she has met her burden under Althen Prong One with a statement offered by Dr. Elizabeth Vaughan, this statement does not comport with the Althen requirements. While medical certainty is not a requirement for a persuasive medical theory connecting the vaccine to petitioner’s injuries, the court cannot accept “cursory, conclusory opinions grounded on the doctor’s instinct.” Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994); See Fadelalla v. Sec’y of Health & Human Servs., No. 97-573V, 1999 WL 270423, at *6 (Fed. Cl. Spec. Mstr. Apr. 15, 1999), mot. for rev. den’d, 45 Fed. Cl. 196 (1999). Expert testimony, in particular, must have some objective scientific basis in order to be credited by the special master. Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999)); Jarvis v. Sec’y of Health & Human Servs., 99 Fed. Cl. 47, 54-55 (2011) (citing Moberly, 592 F.3d at 1322); Cedillo v. Sec’y of Health & Human Servs., 617 F.3d 1328, 1339 (Fed Cir. 2010).

1. Petitioner’s Expert’s Medical Theory

Petitioner’s expert, Dr. Elizabeth Vaughan, is a physician licensed to practice medicine in the State of North Carolina. Pet. Ex. 23 at 29. She received her medical degree from the University of Virginia School of Medicine in 1979. Id. Thereafter, she served a two-year residency in internal medicine at Southwest Michigan Area Health Education Center. Id. She is board certified in internal medicine, emergency medicine, and holistic and integrative medicine.

Id. at 31. Dr. Vaughan is currently a member of the International College of Integrative Medicine, the American Board of Clinical Medical Toxicology, and a Board Member of the North Carolina Integrative Medical Society. Id.

Dr. Vaughan opined that “more than likely the symptoms [petitioner] displayed result[ed] from a toxic reaction to the Gardasil vaccine.” Pet. Ex. 23 at 30. Dr. Vaughan’s expert report did not speak to the hepatitis A or Varivax vaccines. The basis for Dr. Vaughan’s belief that petitioner experienced a toxic reaction to the Gardasil vaccine appears to be based on her determination that petitioner was “immunocompromised, had numerous food sensitivities including gluten intolerance, was deficient in enzymes, had parasites, intestinal candidiasis, and severe nutritional deficiencies.” Id. While Dr. Vaughan summarizes her diagnoses of petitioner, she does not set forth a medical theory or mechanism explaining how the Gardasil vaccine can cause a toxic reaction. Id.

2. Respondent’s Expert’s Response

Respondent’s expert, Dr. Edward Walter Cetaruk, is a medical toxicologist. He is presently an assistant clinical professor of medicine at the University of Colorado Health Sciences Center, Department of Medicine, in the Section of Clinical Pharmacology and Toxicology. Respondent’s Exhibit C at 1. He is also an attending faculty member of the Rock Mountain Poison and Drug Center Fellowship in Medical Toxicology, and an adjunct faculty member at Louisiana State University, National Center for Biomedical Research and Training. Id. Dr. Cetaruk obtained his medical degree at the New York University School of Medicine and is board certified by the American Board of Emergency Medicine with special qualifications in Medical Toxicology. Id.

Dr. Cetaruk notes that Dr. Vaughan does not define the phrase “toxic reaction” or explain how such a reaction caused petitioner’s medical complaints. Exhibit B at 9. Dr. Cetaruk also notes that Dr. Vaughan admits in her report that there are no medical journals or scientific studies to support her conclusions. Finally, Dr. Cetaruk notes that Dr. Vaughan does not “offer a scientifically reliable theory of causation supporting any association between [petitioner’s] Gardasil vaccinations and the development of a ‘toxic reaction’ and/or her medical complaints. Id.

Dr. Cetaruk examines, in detail, the allegation that the vaccine caused a “toxic” exposure to petitioner. He examines the elements of the Gardasil vaccine itself and the petitioner’s complaints. Dr. Cetaruk first analyzes whether the aluminum component of the Gardasil vaccine could cause a toxic exposure leading to injury. He concludes that the “extremely small amounts of aluminum found in vaccines are simply not large enough to result in any pathological condition. Resp’t’s Ex. B at 11-12.

Dr. Cetaruk next examines the other components of the Gardasil vaccine and explains why these components of the vaccine do not cause a toxic reaction. Dr. Cetaruk concludes by stating that he is unaware of any evidence that any of the above discussed vaccine components, when combined together, are known to cause a pathogenic effect. Exhibit B at 14-15.

3. Evaluation of the Evidence

When a petitioner relies upon expert testimony, such testimony must rest upon an objective and reliable scientific basis. Jarvis, 99 Fed. Cl. 47 at 60 (citing Cedillo, 617 F.3d at 1339; Moberly, 592 F.3d at 1324; Terran, 195 F.3d at 1316). Dr. Vaughan does not explain what component of the vaccine was toxic or how that component caused injury to petitioner. See Pet. Ex. 23 at 30. Instead, Dr. Vaughan cites to other case reports of patients with similar symptoms, as well as references to medical blogs. Id. Instead of explaining how a vaccine can cause a toxic reaction, she references her experience with petitioner and a review of some of petitioner's medical records to affirm her opinion that petitioner experienced a toxic reaction. Id. Dr. Cetaruk, in contrast, provides a detailed review of each of the components of the Gardasil vaccine and explains how each component, separately or used together, cannot cause a toxic reaction.

Dr. Vaughan's testimony is conclusory, lacks a scientific basis, and does not contain a medical theory that explains how the Gardasil vaccine can cause the myriad symptoms experienced by petitioner. Accordingly, the expert report is entitled to little, if any, evidentiary weight to establish Althen Prong One. Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 318-19 (7th Cir. 1996); Hines v. Sec'y of Health & Human Servs., 21 Cl. Ct. 634, 646 (1990) (holding that a special master is entitled to give little weight to the conclusory affidavit of a doctor, which contained no additional supporting facts); Fadelalla v. Sec'y of Health & Human Servs., No. 97-573V, 1999 WL 270423, at 6 (Fed. Cl. Spec. Mstr. April 15, 1999), aff'd, 45 Fed. Cl. 196 (1999) ("the court...cannot... [accept] cursory, conclusory opinions grounded on the doctor's instinct.").

Based on the evidence presented by petitioner and respondent, the undersigned finds that petitioner has not provided preponderant evidence of a reliable medical theory connecting her vaccinations and her injuries. Thus, petitioner has not satisfied Althen Prong One.

B. Althen Prong Two

Even assuming that petitioner set forth a reliable medical theory, she cannot satisfy Althen Prong Two. See Caves v. Sec'y of Health & Human Servs., 100 Fed.Cl. 119, 132 (2011) ("When a petitioner seeks to demonstrate causation in fact by meeting the three Althen requirements, *each* of those requirements must be proven by a preponderance of the evidence.") (emphasis added). Althen Prong Two requires petitioner to show a logical sequence of cause and effect demonstrating that the Gardasil vaccination is the cause of her injuries, i.e., the severe cramping, chest pain, back pain, vomiting, abdominal pain, autonomic neuropathy, and fibromyalgia. Althen, 418 F.3d at 1278. To demonstrate "a logical sequence of cause and effect," petitioner must show "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Althen, 418 F.3d at 1278 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999)). In determining whether petitioner has introduced preponderant evidence on the second element of the Althen test, special masters have been instructed to consider the views of treating physicians. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

1. Petitioner's Expert

In her report, Dr. Vaughan summarized petitioner's clinical course after her vaccinations. Pet. Ex. 23 at 29-30. Dr. Vaughan reported that petitioner first experienced chest pain in October 2007 while playing basketball. Id. at 29. Petitioner's chest pain was followed by nausea and vomiting in March 2008. Id. Petitioner continued to experience nausea and vomiting and presented to Yale New Haven Hospital in December 2008. Id. After her discharge from Yale, petitioner was diagnosed with pancreatitis at Duke University Medical Center. She was treated as an outpatient at Duke for several months due to chest pain, malaise, profound fatigue, and uncontrolled nausea and vomiting. Id. at 30.

After petitioner sought treatment at Vaughan Integrative Medicine, Dr. Vaughan opined:

Based on her physical exam and analysis of her stool, blood and saliva I determined that she was immunocompromised, had numerous food sensitivities including gluten intolerance, was deficient in enzymes, had parasites, intestinal candidiasis, and severe nutritional deficiencies. I treated her with medication, nutritional IVs, an elimination diet, supplements and medical foods aimed at enhancing her gastrointestinal function, immune system and nutritional status.

Id.

2. Respondent's Expert's Response

As discussed above, Dr. Cetaruk states in his report that in order to determine whether there is a causal association between the Gardasil vaccine and petitioner's injuries, the vaccine and its components should be examined. Dr. Cetaruk concluded that there is no evidence that any of the components of the Gardasil vaccine, either separately or together, caused petitioner to suffer a toxic reaction.

3. Evaluation of the Evidence

Dr. Vaughan concluded that petitioner was immunocompromised and had numerous other problems, but she does not explain how the problems were caused by vaccine toxicity. Further, Dr. Vaughan did not address petitioner's other diagnoses provided by a myriad of her other treating doctors. Petitioner's treating doctors opined that her abdominal issues were most likely caused by gynecological problems, pancreatitis, IBS, or gallbladder problems. Dr. Vaughan's unsupported observations fail to provide a logical sequence of cause and effect in petitioner's case. Grant, 956 F.2d 1144 (Fed. Cir. 1992) ("A reputable medical or scientific explanation must support [a] logical sequence of cause and effect.").

C. Althen Prong Three

Althen Prong Three requires a petitioner to demonstrate, by a preponderance of the evidence, "a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d

at 1278. This requirement demands “preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact.” Bazan v. Sec’y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008) (citing Pafford v. Sec’y of Health & Human Servs., 451 F.3d 1352, 1358 (Fed.Cir.2006)).

Dr. Vaughan does not address whether the onset of petitioner’s alleged injuries was temporally appropriate. Moreover, Dr. Vaughan does not reference any timeframe that would be appropriate given her conclusion that petitioner had a toxic reaction to her vaccines. While she mentions other case reports of patients who have reported similar symptoms, she does not reference the appropriate temporal relationship between those patients’ vaccinations and the onset of their symptoms. Lastly, a review of the records shows that many of petitioner’s complaints were not temporally related to the vaccinations at issue.

Dr. Cetaruk responded by noting that the toxic reaction Dr. Vaughan alleges was caused by the Gardasil vaccine occurred five months after petitioner’s first Gardasil was administered. Respondent’s Exhibit B at 13. He states that “if a patient were exposed to a ‘toxic’ dose of a substance, one would expect that patient to manifest symptoms consistent with that compound’s known toxic effects within an appropriate time period after the exposure. A delay of such a long period of time argues against any causal association between her Gardasil vaccination ...” Id.

For all of these reasons, the undersigned finds that petitioner has not satisfied Althen Prong 3.

V. Conclusion

In view of the undersigned’s review of the entire record, see § 300aa-13(a)(1), the undersigned finds that petitioner has not provided preponderant evidence that the HPV vaccine or any other vaccine caused her injuries. Althen, 418 F.3d 1274 (Fed. Cir. 2005). For the reasons discussed above, the undersigned finds that petitioner has not established entitlement to compensation and her petition must be dismissed. **Therefore, this case is dismissed for failure to present preponderant evidence under the Althen prongs. The Clerk shall enter judgment accordingly.**

IT IS SO ORDERED.

s/ Nora Beth Dorsey
Nora Beth Dorsey
Special Master